



UNITED STATES PATENT AND TRADEMARK OFFICE

MAR 29 2011

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Office of Regulatory Policy  
Food and Drug Administration  
10903 New Hampshire Ave., Bldg. 51, Rm. 6222  
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

The attached application for patent term extension of U.S. Patent No. RE38,115 was filed on December 17, 2010, under 35 U.S.C. § 156. Please note that an additional patent term extension application has been filed for the same NDA, NDA 22-879, for U.S. Patent No. 5,206,248 for the human drug product NUEDEXTA™ (dextromethorphan hydrobromide/quinidine sulfate) which was filed on December 17, 2010, pursuant to the provisions of 37 C.F.R. § 1.785.

The assistance of your Office is requested in confirming that the product identified in the application, NUEDEXTA™ (dextromethorphan hydrobromide/quinidine sulfate), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use. Additionally, please verify that NDA 22-879 was granted permission for commercial marketing or use on October 29, 2010, so that USPTO can determine that the application for patent term extension was filed within the sixty-day period beginning on the date the product was approved as required by § 156(d)(1).

It is noted that both dextromethorphan hydrobromide and quinidine sulfate have been previously approved by FDA. New Drug Application (NDA) # 012796 was approved on February 21, 1962 for the drug product Quinidex having as the active ingredient, quinidine sulfate (see attached record for NDA # 012796 from Drugs @ FDA<sup>1</sup>). NDA # 011265 was approved on December 3, 1957 for the drug product Promethazine hydrochloride and destromethorphan hydrobromide having the active ingredients dextromethorphan hydrobromide and quinidine hydrochloride (see attached record for NDA # 011265 from Drugs @ FDA). Additionally, NDA # 019279 was approved on August 24, 1984 for the drug product Dimetane-DX having as active ingredients Brompheniramine maleate, dextromethorphan hydrobromide and pseudoephedrine hydrochloride (see attached record for NDA # 019279 from Drugs @ FDA). Since each of the active ingredients in NUEDEXTA has been previously approved by FDA in the NDAs listed above, it does not appear that the permission for the commercial marketing or use of NUEDEXTA meets the requirements of §156(a)(5)(A).

Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

<sup>1</sup><http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

Mary C. Tiff

Mary C. Tiff  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Associate Commissioner  
for Patent Examination Policy

cc: Kevin G. Shaw  
Hogan Lovells US LLP  
555 Thirteenth St., NW  
Washington, DC 20004

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## Drug Details

<b>Drug Name(s)</b>	<b>QUINIDEX (Brand Name Drug)</b>
<b>FDA Application No.</b>	<b>(NDA) 012796</b>
<b>Active Ingredient(s)</b>	<b>QUINIDINE SULFATE</b>
<b>Company</b>	<b>WYETH PHARMS INC</b>
<b>Original Approval or Tentative Approval Date</b>	<b>February 21, 1962</b>
<b>Chemical Type</b>	<b>3 New formulation</b>
<b>Review Classification</b>	<b>P Priority review drug</b>

- There are no Therapeutic Equivalents
- [Label Information](#)
- [Approval History, Letters, Reviews, and Related Documents](#)

### Products on Application (NDA) #012796

Click on a column header to re-sort the table:

<b>Drug Name</b>	<b>Active Ingredients</b>	<b>Strength</b>	<b>Dosage Form/Route</b>	<b>Marketing Status</b>	<b>RLD TE Code</b>
QUINIDEX	QUINIDINE SULFATE	300MG	TABLET, EXTENDED RELEASE; ORAL	Discontinued	No None

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## Drug Details

<b>Drug Name(s)</b>	DIMETANE-DX (Brand Name Drug)
<b>FDA Application No.</b>	(NDA) 019279
<b>Active Ingredient(s)</b>	BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PSEUDOEPHEDRINE HYDROCHLORIDE
<b>Company</b>	ROBINS AH
<b>Original Approval or Tentative Approval Date</b>	August 24, 1984
<b>Chemical Type</b>	3 New formulation
<b>Review Classification</b>	S Standard review drug

- There are no Therapeutic Equivalents
- Labels are not available
- [Approval History, Letters, Reviews, and Related Documents](#)

### Products on Application (NDA) #019279

Click on a column header to re-sort the table:

<u>Drug Name</u>	<u>Active Ingredients</u>	<u>Strength</u>	<u>Dosage Form/Route</u>	<u>Marketing Status</u>	<u>RLD</u>	<u>TE Code</u>
DIMETANE-DX	BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PSEUDOEPHEDRINE HYDROCHLORIDE	2MG/5ML; 10MG/5ML; 30MG/5ML	SYRUP; ORAL	Discontinued	No	None

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## Drug Details

Drug Name(s)	PROMETHAZINE HYDROCHLORIDE AND DESTROMETHORPHAN HYDROBROMIDE (Brand Name Drug)
FDA Application No.	(NDA) 011265
Active Ingredient(s)	DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE
Company	ANI PHARMS
Original Approval or Tentative Approval Date	December 3, 1957
Chemical Type	4 New combination
Review Classification	S Standard review drug

- There are no Therapeutic Equivalents
- [Label Information](#)
- [Approval History, Letters, Reviews, and Related Documents](#)

### Products on Application (NDA) #011265

Click on a column header to re-sort the table:

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	RLD TE Code
PROMETHAZINE HYDROCHLORIDE AND DESTROMETHORPHAN HYDROBROMIDE	DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE	15MG/5ML; 6.25MG/5ML	SYRUP; ORAL	Discontinued	No None

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